Subject: FR Notice Comments - 74FR14556 - Ocular Peer Panel Meeting
Date: Thursday, May 14, 2009 10:47 AM

Below is the result of your feedback form. It was submitted by
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Comment_date: May 14, 2009

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Comments: May 14, 2009

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Dear Dr. Stokes,

This public comment is delivered in response to Federal Register Notice Volume 74, Number 60, Pages 14556-14557. It provides some overview comments from the European Cosmetics Association COLIPA on the Background Review Documents (BRDs) published on April 1, 2009 indicates

COLIPA's intention to be present at the public meeting of the peer review panel meeting to be held on May 19-21, 2009.

COLIPA very much welcomes this activity of ICCVAM to address the Validation Status of Alternative Ocular Safety Testing Methods and Approaches.

As you are aware, COLIPA has been and remains very active in the area of eye irritation alternatives. Our goal is the development and validation of in vitro methods that are more predictive of the human response through better understanding of chemically induced mechanisms of eye irritation. Our overall programme focuses on: 1) development/optimisation of in vitro methods for validation and 2) research on identification and integration of evaluation endpoints based on mechanistic understanding into existing/new in vitro test methods. In light of this, we would like to offer the following general overview comments:

- We acknowledge that replacement of the in vivo test will require combinations of in vitro assays. We would welcome discussion on the possibility of statistical approaches that will be necessary to allow decision making from complex matrices of data on individual in vitro assays and their domains of applicability in a tiered testing strategy.

- We would encourage primary use of specific domains of applicability to define the acceptability of an in vitro assay to predict a defined level of eye irritation. This would favour more correct prediction of classification using combinations of in vitro assays in a tiered testing strategy.

- We would welcome discussion on use of a Weight of Evidence (WoE) approach to identify the in vivo reference standard against which to validate in vitro test methods. This would include discussion of the role of human experience data from Poison Control Centres and industry (cosmeto/pharmacoviligance) systems. Data from these sources can span more than four decades.

- We are presented with an important opportunity to use a WoE approach to further retrospective analysis to

validate alternative methods/strategies for eye irritation and identify future research and validation needs.

- Such retrospective analysis would allow us to identify further research needs on mechanisms of chemically induced eye irritation e.g. physiological mechanisms involved in reversible injury which are key to prediction of eye corrosives and severe eye irritants.

- We would welcome further discussion on harmonisation of approaches/activities for retrospective validation of in vitro assays for eye irritation in the context of the recently established International Cooperation on Alternative Test Methods (ICATM).
